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EPAR summary for the public

Meloxivet

Meloxicam

This document is a summary of the European Public Assessment Report. Its purpose is to explain how the assessment done by the Committee for Medicinal Products for Veterinary Use (CVMP) on the basis of the documentation provided, led to the recommendations on the conditions of use.

This document cannot replace a face-to-face discussion with your veterinarian. If you need more information about your animal's medical condition or treatment, contact your veterinarian. If you want more information on the basis of the CVMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is Meloxivet?

Meloxivet is a white to yellowish opaque oral suspension which is to be given mixed with food.

Meloxivet contains the active substance meloxicam and exists in 2 different strengths (0.5 and 1.5 mg/ml, respectively). Meloxivet is a 'generic': this means that Meloxivet is similar to a 'reference veterinary medicine' already authorised in the EU (Metacam 1.5 mg/ml oral suspension). Studies have been carried out to prove that Meloxivet is 'bioequivalent' to the reference veterinary medicine: this means that Meloxivet is equivalent to Metacam 1.5 mg/ml suspension in the way it is absorbed and used by the body.

What is Meloxivet used for?

Meloxivet is used in dogs to relieve inflammation and pain in musculo-skeletal disorders. It can be used for both acute disorders, such as those seen after an injury, and chronic (long term) disorders.

Meloxivet is given to the dog once a day, with food, at the dose of 0.2 mg/kg on the first day, then as 0.1 mg/kg afterwards. The amount of suspension to be used is measured using a special dosing syringe (provided in the package), and poured on the food.

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How does Meloxivet work?

Meloxivet contains meloxicam, which belongs to a class of medicines called nonsteroidal anti-inflammatory drugs (NSAIDs). Meloxicam acts by inhibition of prostaglandin synthesis. As the prostaglandins are substances that trigger inflammation, pain, exudation and fever, meloxicam reduces those responses.

How has the effectiveness of Meloxivet been studied?

A study looked at how Meloxivet was absorbed and its effects in the body, in comparison with Metacam 1.5 mg/ml oral suspension.

What are the side-effects of Meloxivet?

Occasional side effects of Meloxivet are those seen with NSAIDs, such as loss of appetite, vomiting, diarrhoea, blood appearing in the stools and apathy (lack of vitality).

These side effects occur usually within the first week of treatment and are generally transient (temporary). They disappear once treatment has stopped. In very rare cases, they may be serious or fatal.

What are the precautions for the person who gives the medicine or comes into contact with the animal?

People who are hypersensitive (allergic) to NSAIDs should avoid contact with Meloxivet.

If the product is swallowed by a person, the advice of a doctor should be sought immediately.

Why has Meloxivet been approved?

The Committee for Medicinal Products for Veterinary Use (CVMP) considered that, in accordance with European Union requirements, Meloxivet has been shown to be bioequivalent to Metacam 1.5 mg/ml oral suspension. Therefore the CVMP's view was that, as for Metacam 1.5 mg/ml oral suspension, Meloxivet's benefits are greater than its risks when treating inflammation or pain in muscles or joints in dogs and they recommended that Meloxivet should be given a marketing authorisation. The benefit-risk balance may be found in the scientific discussion module of this EPAR.

Other information about Meloxivet:

The European Commission granted a marketing authorisation valid throughout the European Union, for Meloxivet on 14 November 2007 Information on the prescription status of this product may be found on the label of the carton.

This summary was last updated: March 2012.